K012344

OCT 04 2002

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
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Date

July 31, 2001

Device

- Trade Names: Vanguard Reprocessed Pulse Oximeter Sensors
  ⇒ Mallinckrodt, Inc., Nellcor:
  - N-25: Oxisensor® II neonatal/adult sensor
  - D-25L: Oxisensor® II adult sensor, long cable
  - D-25: Oxisensor® II adult sensor
  - D-20: Oxisensor® II pediatric sensor
  - I-20: Oxisensor® II infant sensor
- Common Name: Pulse oximeter sensor, oxygen transducer
- Classification: 21 CFR 870.2700 – Oximeter – Class II
- Product Code DQA

Predicate Device

Respective Mallinckrodt, Inc., Nellcor Oxisensor® II Sensors legally marketed under various 510(k) premarket notifications.

Indications for Use

The sensor is indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Contra-indications

This device should not be used on patients who exhibit allergic reactions to the adhesive tape.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description

Oximeter sensors are used with compatible pulse oximeters to noninvasively continually monitor oxygen saturation and pulse rate. The primary components of the sensors are light-emitting diodes (red and infrared LED) and a photosensor. These components are embedded within a taping system to wrap the sensor around a patient's finger, foot or hand so that the LED and photosensor are directly opposite each other. As light is emitted and received across the vascular bed, the rates of absorption at the two wavelengths vary depending upon the ratios of oxygenated and deoxygenated hemoglobin within the blood. The pulse oximeter detects the changes in absorption and utilizes an algorithm to calculate the corresponding pulse rate (beats/minute) and percent arterial oxygen saturation.

Vanguard receives previously used oximeter sensors from healthcare facilities; cleans, reworks, (replaces the tape [all patient-contacting materials]), inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

Technological Characteristics

The Vanguard reprocessed oximeter sensors are essentially identical to the currently marketed OEM sensors. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Test Data

Sterilization validations, and functional/performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed pulse oximeter sensors are substantially equivalent to the predicate devices, Mallinckrodt, Inc., Nellcor Oxisensor® II Sensors, under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 04 2002

Dr. Mike Sammon
Director, Research and Development
Vanguard Medical Concepts, Incorporated
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K012344
Trade/Device Name: Vanguard Reprocessed Pulse Oximeter Sensors
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: 74 DQA
Dated: July 25, 2002
Received: July 29, 2002

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cuccinelli/for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K012344

Device Name: Vanguard Reprocessed Pulse Oximeter Sensors

Indications for Use:

The sensor is indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K012344